IN THE FOOD AND DRUG ADMINISTRATION

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Petition for Regulation of Ariva™ Tobacco Lozenges	)	Docket No. 01P-0572

STAR SCIENTIFIC, INC., COMMENTS ON CITIZEN PETITION FOR REGULATION OF ARIVA™

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INTRODUCTION

Star Scientific, Inc. submits this response to oppose a Citizen Petition filed on December 18, 2001 asking the Food and Drug Administration (FDA) to regulate Ariva™ (Ariva) compressed smokeless tobacco "cigalett"™ (cigalett) pieces as "drugs" or "foods" within the meaning of the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq.* As we explain in detail below, the Petition should be denied, because it is based on the factually erroneous assertion that Ariva is a "candy" or "confectionery" intended to treat the disease of nicotine addiction. Instead, Ariva is a compressed, powdered tobacco product intended to be used by adult tobacco users for tobacco satisfaction, as are cigarettes, snuff or other smokeless tobacco products. The Bureau of Alcohol, Tobacco and Firearms (BATF) has classified Ariva as a "snuff" subject to the federal excise tax and licensing requirements applicable to the manufacture and sale of smokeless tobacco products, 26 U.S.C. § 5701, *et seq.*, and Ariva is subject to the warning requirements of the Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. §§ 4401-4408, and implementing Federal Trade Commission (FTC) regulations. Thus, under the Supreme Court's decision in *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120

(2000), Ariva is a tobacco product that is outside the scope of FDA's jurisdiction.

Star Scientific has advocated that Congress give FDA comprehensive jurisdiction to regulate the manufacture, sale, distribution, labeling and marketing of *all* tobacco products.[1] To date, Congress has not given FDA this authority. Until Congress acts, *Brown & Williamson* deprives FDA of authority to regulate tobacco products, absent claims of therapeutic benefit by the manufacturer. As Petitioners state, Star Scientific has "decided to market Ariva without those claims." (Petition at 18). Therefore, Ariva, like other tobacco products, falls outside the scope of FDA's present jurisdiction.

STATEMENT OF FACTS

Star Scientific is a technology-oriented tobacco company with a mission centered upon the reduction of toxins in tobacco leaf and tobacco smoke. Star Scientific has developed and implemented a patented and commercially feasible non-chemical (StarCured™) tobacco curing technology that significantly reduces the formation of tobacco-specific nitrosamines (TSNAs), which respected scientists believe are cancer-causing toxins in tobacco leaf. In addition to sublicensing this tobacco curing technology to other companies, Star Scientific is engaged in the

[1] See Star Scientific Policy Statement (Attachment 1).

development of tobacco products using StarCured™ tobacco.[2] One of these tobacco products is Ariva, which Star Scientific began selling on November 14, 2001 in test-markets in Dallas, Texas and Richmond, Virginia.[3]

The ingredients in Ariva are identical to those in Stonewall™ dry snuff, another of Star Scientific's smokeless tobacco products. Both Ariva and Stonewall dry snuff are made of powdered Virginia StarCured™ tobacco and contain mint, eucalyptus and other natural and artificial flavorings and ingredients that are commonly found in smokeless tobacco products and cigarettes. The only difference between the two smokeless tobacco products is that Ariva is compressed into cigalett pieces.

Because nicotine is a naturally occurring alkaloid in tobacco, and the primary ingredient in Ariva is powdered tobacco, Ariva contains the same natural nicotine as do all other smokeless and smoked tobacco products.

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[2] Star Scientific previously developed a low-TSNA premium cigarette, called Advance™, that used StarCured tobacco and contained an activated charcoal filter which reduced certain gas-phase toxins. Advance™ is the subject of another Citizen Petition filed by Petitioners. But as explained in the press release attached as Attachment A to the Petition, Star Scientific entered into an agreement under which Brown & Williamson took over the marketing and manufacture of Advance.

[3] See Press Release, Star Scientific, Inc., "Star Scientific Announces Test Market of Ariva Smokeless Tobacco Cigaletts" (Attachment 2).

The level of nicotine in an Ariva cigalett is comparable to that in a light cigarette.[4]

Ariva is a smokeless tobacco product for adult smokers who find themselves in situations and environments where they cannot, or do not want to, smoke and for smokeless tobacco users who want a smokeless tobacco product that does not require expectoration.[5] A package of 20 Ariva cigaletts sells for a retail price of around four dollars, which is comparable to the cost of premium cigarettes and snuff.

Because Ariva is a smokeless tobacco product, its packaging contains the health warnings required by the Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. § 4402, and the implementing FTC regulations, 16 C.F.R. § 307.2. As required by those regulations, each package of Ariva contains one of the following warnings:

(1) WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER;

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[4] See Star Scientific, "QUESTIONS AND ANSWERS", a Fact Sheet for Distribution to Public Health Colleagues, at 2 (Attachment 3).

[5] See Press Release, Star Scientific, "Star Scientific And B&W Enter Into Contracts for Purpose Of StarCured Tobacco, Development and Sale of Very-Low TSNA Smoked and Smokeless Tobacco Products," at 1 (Attachment A to the Petition).

(2) WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS;

(3) WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES.

16 C.F.R. § 307.4(a); see also 15 U.S.C. § 4402(a)(1).

The Bureau of Alcohol, Tobacco and Firearms (BATF) has determined that Ariva is a "smokeless tobacco product" within the meaning of the Internal Revenue Code, which imposes federal excise taxes on tobacco products and requires businesses engaged in the manufacture of tobacco products to obtain a license from BATF.[6] 26 U.S.C. § 5701, *et seq.* BATF granted Star Scientific a license to manufacture Ariva, and Ariva is taxed as a "snuff" tobacco product. This is the same tax designation that is applied to Stonewall dry snuff.

Ariva is sold under the same rules, regulations and requirements that govern all tobacco products.[7] Thus, Ariva is kept in the same location in

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[6] The Internal Revenue Code defines "smokeless tobacco" as "any snuff or chewing tobacco" and defines "snuff" as "any finely cut, ground, or powdered tobacco that is not intended to be smoked." 26 U.S.C. §§ 5702(m)(1), 5702(m)(2); see also 27 C.F.R. § 275.11 (same definition in BATF regulations).

[7] See QUESTIONS AND ANSWERS, *supra* note 4, at 3.

stores as other tobacco products, and purchase requires valid proof of age.[8] In addition, each package of Ariva includes the following prominent labeling: "Underage Sale Prohibited", and "THIS PRODUCT IS FOR ADULT TOBACCO USERS ONLY".[9]

Ariva is also the first tobacco product to use child-resistant packaging: The cigalett pieces are sold in blister packs of 20. Star Scientific chose this packaging after reviewing poison control data on the annual incidence of toxicity arising from toddlers' accidental ingestion of tobacco products.[10]

Although the label states that Ariva contains StarCured™ tobacco, it does not state that Ariva contains lower nitrosamines.[11] Nor does Star Scientific make any health claims for Ariva. Star Scientific has repeatedly stated that Ariva is not a smoking cessation product, but rather is a smokeless tobacco product for use by adult tobacco users.[12] And Star Scientific clearly acknowledges the health hazards associated with the use of

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[8] See, Star Scientific, "WHAT IS ARIVA™?", a Fact Sheet for Distribution to Public Health Colleagues (Attachment 4).

[9] ARIVA™ Label (Attachment 5).

[10] ARIVA™ FACT SHEET (Attachment 6).

[11] QUESTIONS AND ANSWERS, *supra* note 4, at 2

[12] See, *e.g.*, WHAT IS ARIVA™?, *supra* note 8; QUESTIONS AND ANSWERS, *supra* note 4, at 4.

all tobacco products, including those made with StarCured™ tobacco.[13] Thus, in addition to the health warnings required by federal law, the Ariva package features an additional warning that states:

"There are No safe tobacco products.
Quitting or Not starting is your best option."[14]

REASONS FOR DENYING THE PETITION

1. Ariva Cigaletts Are Not "Drugs" Within The Meaning Of The FDCA.

a. Ariva Is A Smokeless Tobacco Product That Is Outside The Scope Of The FDCA As Interpreted By The Supreme Court In *Brown & Williamson.*

As Petitioners correctly note (Petition at 4), the FDCA defines "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals," and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. §§ 321(g)(1)(B), 321(g)(1)(C). Petitioners' principal argument is that Ariva cigaletts are "drugs" within the meaning of the statute because they deliver nicotine to the user to "treat"

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[13] See Star Scientific Policy Statement, *supra* note 1.

[14] ARIVA™ Label, *supra* note 9.

nicotine addiction and to affect the structure and function of the body. (Petition at 4-10).

Unlike some other tobacco companies, Star Scientific does not dispute that nicotine is addictive and affects the structure and function of the body. Nor does Star Scientific dispute that Ariva contains natural nicotine alkaloid. On the contrary, the Ariva label expressly states that "All tobacco products -- including Ariva™ -- contain nicotine, an **addictive** substance."[15] As noted above, the amount of nicotine in an Ariva cigalett is comparable to that in a light cigarette. But to end the analysis there overlooks the critical fact that *Ariva contains natural nicotine alkaloid because it is a tobacco product like cigars, cigarettes, snuff and chewing tobacco.* As FDA concluded in the rulemaking to restrict the sale and distribution of cigarettes and smokeless tobacco products to children and adolescents, *all* tobacco products could be classified as "drugs" because they contain nicotine, which has "significant pharmacological effects," and thus "affect the structure or any function of the body." *Brown & Williamson*, 529 U.S. at 127 (quoting 61 Fed. Reg. at 44631). Nevertheless, in *Brown & Williamson* the Supreme Court held that

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[15] Ariva Label, *supra* note 9 (emphasis included on the Ariva label).

> Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products. Such authority is inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the FDCA. In light of this clear intent, the FDA's assertion of jurisdiction is impermissible.

529 U.S. at 126. That conclusion applies squarely to Ariva as well.

Instead of subjecting tobacco products to the FDCA, Congress created "a distinct regulatory scheme for cigarettes and smokeless tobacco." *Brown & Williamson*, 529 U.S. at 155. This distinct regulatory scheme forecloses the removal of tobacco products from the market and addresses the "problem of tobacco and health" through tobacco-specific labeling laws, such as the Federal Cigarette Labeling and Advertising Act (FCLAA), and the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA). *Id.* at 137.

Congress adopted these tobacco labeling laws against the backdrop of FDA's consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco products unless the manufacturer claimed that the tobacco product would have a therapeutic benefit to the user. *Id.* at 144. Moreover, Congress "considered and rejected bills that would have granted the FDA such jurisdiction." *Id.* Instead, Congress decided to subject cigarettes to the FCLAA, which regulates cigarette labeling and advertising

with respect to any relationship between smoking and health, *id.* at 148, and to subject smokeless tobacco products to the similar labeling and advertising restrictions in the CSTHEA, *id.* at 154. "Under these circumstances," the Court concluded, "Congress' tobacco-specific legislation has effectively ratified the FDA's previous position that it lacks jurisdiction to regulate tobacco." *Id.* at 156.

That holding compels the conclusion that FDA lacks jurisdiction to regulate Ariva. Ariva is a "smokeless tobacco" product within the meaning of the CSTHEA -- a statute which Petitioners completely ignore. The CSTHEA defines "smokeless tobacco" as "any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity." 15 U.S.C. § 4408(1). Ariva falls squarely within that definition. As explained above, Ariva is composed of powdered tobacco that is compressed into a cigalett intended to be placed in the oral cavity. Ariva also contains the flavorings that are contained in Stonewall dry snuff and are commonly used in other smokeless tobacco products as well. Indeed, Ariva is nothing more than a compressed version of Stonewall dry snuff. See *supra* at 3.

Petitioners nonetheless assert that Ariva is not a smokeless tobacco product because consumers of Ariva will not have to expectorate. (Petition at 15). They are wrong. The CSTHEA does not make expectoration a

defining attribute of a "smokeless tobacco" product; indeed, expectoration is not mentioned in the statutory definition at all. Smokeless tobacco products come in many forms, including powdered snuff, whole or ground loose leaf tobacco, individual pouches, and hardened blocks or ropes of tobacco. These products are frequently advertised as containing flavorings such as menthol, eucalyptus, spearmint, citrus, vanilla, wintergreen, cherry, lemon, and even Irish Whiskey.[16] Some of these products are intended to dissolve

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[16] On April 26, 2002, as we were preparing to file this response to the Petition, GlaxoSmithKline Consumer Healthcare submitted a comment including what it claims is an analysis of the chemical constituents of Ariva. Glaxo argues that this analysis demonstrates that Ariva is not simply a "compressed hard tobacco product" because Ariva contains, among other things, "sweeteners" and "flavoring ingredients." Glaxo Comment at 2. We have not had time to review the Comment in detail, and we reserve the right to make additional submissions in response to this Comment at a later date. But even assuming, for the sake of argument, the accuracy of Glaxo's chemical analysis, it does not establish that Ariva is a "food" or "drug" within the meaning of the FDCA, as Glaxo claims (at 2 & n.5). As we discuss in the text above, tobacco products typically contain sweeteners and natural and artificial flavorings and ingredients. See Snuff Types, available at <<http://www.snuffshop.com>>; and Snuff Products, available at <<http://www.cigarettesamerica.com>>. Indeed, it is notable that Glaxo did not compare Ariva's alleged constituent elements with those of other undoubted tobacco products, such as cigarettes and moist and dry snuffs.

The Glaxo Comment also erroneously states that Star Scientific has made Ariva available for sale over the Internet. See Glaxo Comment at 2. Star Scientific does not sell Ariva over the Internet, and it monitors the Internet in an attempt to prevent tobacco distributors from engaging in such sales. After Star Scientific contacted the Internet tobacco distributor identified in the Glaxo Comment, the distributor removed Ariva from its list

in the oral cavity and do not require expectoration. For example, dry snuff can be rubbed on the gums and allowed to dissolve in the mouth as does Ariva.[17] There are also chewing tobacco bits that are intended to dissolve in the mouth and contain labels stating that expectoration is not required.[18] The CSTHEA's definition of "smokeless tobacco" encompasses all of these forms, because it includes "*any* finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity." 15 U.S.C. § 4408(1) (emphasis added).

Moreover, Petitioners misstate the holding of *Brown & Williamson* by claiming that it held only that FDA lacks jurisdiction to regulate what Petitioners deem to be "conventional" or "traditional" tobacco products. (Petition at 16-17). These terms -- which Petitioners define as "cigarettes, cigars, pipe tobacco, and conventional forms of chewing tobacco and snuff" (*id.* at 17) -- are not found in either the *Brown & Williamson* decision or the

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of available tobacco products and now notes: "Sorry! This tobacco product is no longer available at this time."

[17] As far as we have been able to determine, there are approximately ten manufacturers and approximately 75-80 different brands of dry snuff.

[18] For example, the label from Oliver Twist Chewing Tobacco Bits describes the product as a "Smokeless tobacco" that the consumer should "keep between gum and cheek -- don't chew -- it's long lasting and slowly melts giving you secret tobacco satisfaction without expectorating." (Attachment 7).

tobacco-specific statutes on which the Court relied. Instead, *Brown & Williamson* held that "there is no room for *tobacco products* within the FDCA's regulatory scheme" (529 U.S. at 143 (emphasis added)) and that "Congress' tobacco-specific statutes preclude the FDA from regulating *tobacco products as customarily marketed*" (*id.* at 156 (emphasis added)). It is clear, moreover, that the Supreme Court used the term "tobacco products as customarily marketed" in the same way that FDA used the term in the challenged rulemaking and subsequent litigation -- that is, to refer to tobacco products marketed "without manufacturer claims of therapeutic benefit." *Brown & Williamson*, 529 U.S. at 127; see also *Brown & Williamson Tobacco Corp.* v. *FDA*, 153 F.3d 155, 161 n.9 (4th Cir. 1998) (noting that FDA's brief used the term "customarily marketed" to indicate "tobacco products with customary claims such as smoking pleasure as opposed to tobacco products marketed with specific therapeutic claims such as weight loss"), *aff'd*, 529 U.S. 120 (2000); Petition for Writ of Certiorari, *FDA* v. *Brown & Williamson Tobacco Corp.*, No. 98-1152 at 12, n.3 (noting FDA's agreement with the Fourth Circuit's use of the term "customarily marketed").

Thus, Petitioners' attempt to portray Ariva as a "non-traditional" smokeless tobacco product does not take the product outside the holding in *Brown & Williamson*. Ariva is a "smokeless tobacco" product within the

meaning of the CSTHEA, on which the *Brown & Williamson* Court relied. It is, therefore, a "tobacco product" that falls outside the FDCA's regulatory scheme, absent claims of therapeutic benefit by the manufacturer, which, as we explain below (and Petitioners concede), Star Scientific does not make.

Because Ariva is a tobacco product, it cannot be analogized to FDA-approved pharmaceutical drugs products, like the nicotine patch, nicotine gum, and the nicotine inhaler, as Petitioners maintain. (Petition at 4-6). These non-tobacco products, which FDA regulates as "drugs" under the FDCA, are marketed as aids for smoking cessation.[19] Intended to be used by people who want to *quit smoking*, these smoking cessation products "partially replace[] the nicotine derived from tobacco" to "help[] reduce withdrawal symptoms" and "take the edge off [the] craving" to smoke.[20] Ariva, in contrast, is a smokeless tobacco product that provides nicotine to

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[19] Similarly, FDA recently warned pharmacies that nicotine lollipops and nicotine lip balm are "drugs" that cannot be sold without prior FDA approval because the products are promoted "as aids for smoking cessation or to treat nicotine addiction" and contain a "drug substance, nicotine salicylate, which is not permitted for use by pharmacists in compounding drugs." FDA Talk Paper, *FDA Warns Sellers of Nicotine Lollipops & Lip Balm That Their Products Are Illegal* (April 10, 2002), available at <<http:\\www.fda.gov/bbs/topics/ANSWERS/2002/ANS01144.html>>. These products are thus distinguishable from Ariva, which is not a smoking cessation aid, but rather is a smokeless tobacco product that provides nicotine as a natural byproduct of its presence in the tobacco leaf, as do all tobacco products.

[20] The Science of NRT, at 1-2 (Attachment B to the Petition).

the user in the same way that other tobacco products provide nicotine -- as a natural byproduct of its presence in the tobacco leaf.[21] It is also marketed as are other smokeless tobacco products, without claims of therapeutic benefit.[22] Ariva is, therefore, a tobacco product that is outside the scope of the FDCA.

b. Because Star Scientific Makes No Claims of Therapeutic Benefit for Ariva, This Is Not The Unusual Case In Which FDA Can Assert Jurisdiction Over a Tobacco Product.

As discussed above, the Supreme Court in *Brown & Williamson* held that FDA lacked "jurisdiction under the FDCA to regulate tobacco products as customarily marketed -- that is, without manufacturer claims of

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[21] Indeed, in the Petition for Regulation of R.J. Reynolds' "Eclipse Product" that Petitioners filed on the same day as they filed this Petition for Regulation of Ariva, Petitioners use this definition of a "traditional tobacco product" -- i.e., one that provides nicotine "as a natural consequence of its presence in the tobacco leaf" -- to distinguish tobacco products that they concede to be outside of the FDA's regulatory authority under *Brown & Williamson* from those that they believe FDA continues to have jurisdiction to regulate. See Petition for Regulation of R.J.Reynolds "Eclipse Product" at 17.

[22] Ariva is marketed for "WHEN YOU CAN'T SMOKE"™ (Ariva Label, *supra* note 9), which is the type of slogan that is commonly used to market smokeless tobacco products to smokers. See Advertisements for Skoal Flavor Packs (Attachment 8). Star Scientific's use of this slogan is therefore consistent with the advertising of other smokeless tobacco products and does not suggest that Ariva is "functionally analogous to nicotine-substitution products," as Petitioners maintain (Petition at 6).

therapeutic benefit." 529 U.S. at 127. Thus, the Court did not question FDA's authority to regulate tobacco products in the unusual case in which a manufacturer claims that the product has a therepeutic benefit, such as weight loss. *Supra* at 13.

Petitioners concede that Star Scientific is not making "explicit health claims in connection with marketing Ariva." (Petition at 12). Nevertheless, they assert that Star Scientific's previous statements that StarCured™ tobacco contains far lower levels of carcinogenic tobacco-specific nitrosamines (TSNAs) than are found in conventionally cured tobacco provide a basis for FDA to investigate whether there may be grounds for a future assertion of FDA jurisdiction over Ariva. *Id.* Petitioners are wrong.

As explained above, the label states that Ariva contains StarCured™ tobacco, but does not state that Ariva contains "lower nitrosamines." See *supra* at 6. In addition, each Ariva package contains one of the three warning statements for smokeless tobacco products required by the CSTHEA and the implementing regulations promulgated by the Federal Trade Commission. See 15 U.S.C. § 4402(a)(1); 16 C.F.R. § 307.4(a); and *supra* at 4. Star Scientific has also included the following, additional warning on Ariva packages:

"There are No safe tobacco products.

Quitting or Not starting is your best option."

See *supra* at 7.

Moreover, Star Scientific has repeatedly stated that "there is no proof that reducing the TSNAs in Ariva™ will lead to a reduction in the health risk associated with its use,"[23] and has publicly acknowledged that "[a]dditional studies must be undertaken to demonstrate that TSNA reductions in smokeless tobacco leads to reduced risk of oral cancer."[24] Thus, Star Scientific has not made any health or drug claims about Ariva,[25]

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[23] Star Scientific, "TOBACCO SPECIFIC NITROSAMINES," a Fact Sheet for Distribution to Public Health Colleagues (Attachment 9); see also, *e.g.*, QUESTIONS AND ANSWERS, *supra* note 4, at 1 ("there is currently no proof that lowering nitrosamines will decrease health risk").

[24] QUESTIONS AND ANSWERS, *supra* note 4, at 1.

[25] Ariva is therefore distinguishable from the GumSmoke example cited in the Petition (at 11). Gumsmoke was a tobacco flavored chewing gum that was subject to FDA regulation as a food, because gum is expressly included in the FDCA definition of "food." See *infra* at 22. In addition, a FDA compliance officer in the letter quoted in the Petition expressed his concern that the proposed marketing of a gum containing small amounts of tobacco might convey the impression that it was a safe and effective product for "people who want to quit smoking." Letter from Kevin M. Budich, Compliance Officer, OTC Compliance Team (HFD-312) to Paul Perito, dated July 22, 1998, at 3 (Attachment E to the Petition). In contrast, Star Scientific has not made any "smoking cessation claims" about Ariva See *supra* at 6. And as a smokeless tobacco product, Ariva is subject to the regulation, control and labeling requirements applicable to smokeless

and there is no basis for FDA to conduct an investigation.[26]

2. Ariva Cigaletts Are Not "Foods" Containing A "Food Additive" Within The Meaning Of The FDCA.

Petitioners' final contention is that Ariva cigaletts should be considered an adulterated "food" containing a "food additive" (tobacco) that is not generally recognized as safe for use in foods. (Petition at 12-16). That contention should be rejected for two independent reasons. First, Ariva is not a "food" within the meaning of the FDCA (and, therefore, the tobacco in Ariva is not a "food additive" either). Second, the reasoning the Supreme

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tobacco products, which would clearly negate any such inference about Ariva.

[26] As noted above, Star Scientific's statements that Ariva contains lower nitrosamines cannot be interpreted as a claim that Ariva poses less risk than do other tobacco products, because Star Scientific has repeatedly stated that there is no proof that reducing the TSNAs in Ariva will lead to a reduction in the health risk associated with its use. But even if Star Scientific's statements were interpreted as claims that Ariva poses less health risk to consumers, FDA would still lack jurisdiction over Ariva because the agency has previously disavowed that it has jurisdiction to regulate reduced-risk claims for tobacco products. See Letter from Mark Novitch for Jere E. Goylan, Commissioner of Food and Drugs, to John F. Banshaf, II and Peter Georgiades (Nov. 25, 1980) (rejecting Citizen Petition to regulate attached and detached cigarette filters as medical devices) (Attachment 10). This letter was cited in *Brown & Williamson*, 529 U.S. at 153, as evidence of FDA's longstanding understanding of its jurisdiction under the FDCA. See also *FTC* v. *Liggett & Myers Tobacco Co.*, 108 F. Supp. 575 (S.D.N.Y. 1952) (a claim that a tobacco product has a "non-adverse effect" on the user is not a drug claim under the identical "drug" definition in the Federal Trade Commission Act), *aff'd* 203 F.2d 955 (2d Cir. 1953).

Court used in holding that tobacco products are outside the scope of the "drug" provisions of the FDCA is equally applicable to the "food" provisions of the statute. Thus FDA lacks jurisdiction to regulate Ariva as a food.

a. Ariva is not a "food" within the meaning of the FDCA. That statute defines "food" as "articles used for food or drink for man or other animals;" a "chewing gum," or "articles used for components of any such article." 21 U.S.C. § 321(f). Petitioners do not claim that Ariva is a chewing gum or a component of some food product. Instead, they claim that Ariva is "an "article[] used for food," 21 U.S.C. § 321(f)(1), that is, it is "used by people in the ordinary way most people use food -- primarily for taste, aroma or nutritive value." *Nutrilab, Inc.* v. *Schweiker*, 713 F.2d 335, 337 (7th Cir. 1983). But Petitioners have no support for this claim other than their bald assertion that Ariva must be used for food, because, in their view, Ariva is a "mint tasting candy," "comparable to a Tic-tac mint." (Petition at 12, 13). Petitioners are wrong.

Certainly people use Ariva because they like it: they like the tobacco satisfaction it provides. But if that makes Ariva a "food," then so are cigarettes, snuff and chewing tobacco foods, which plainly they are not. This argument is one more example of Petitioners' unwillingness to accept the teaching of *Brown & Williamson* that Congress in the FCLAA and the

CSTHEA has devised a distinct regulatory regime for tobacco products, and that other regulatory regimes are not to be twisted into applications Congress did not intend. See *infra* at 22-24.

Moreover, Petitioners' speculation that Ariva is "like a food in its very form" and "will be used as mint tasting candy" (Petition at 12) finds no support in the record. As discussed in detail above, Ariva is not a "mint tasting candy." It is a compressed version of Stonewall dry snuff, a smokeless tobacco product that no one has ever suggested is like a candy or "used for food." The only difference between Stonewall dry snuff and Ariva is that Ariva is compressed into a hard pellet, while Stonewall dry snuff remains in powdered form. The ingredients in the two smokeless tobacco products are exactly the same, and there is no "candy" coating added to the Ariva cigalett. See *supra* at 3. Consequently, Ariva does not taste like candy. Instead, it has a tobacco taste, described by some as slightly bitter.[27]

Nor is Ariva marketed as a candy. The Ariva package does not claim that the product is a candy, or even mention that it has a mint flavor. Instead, Ariva is marketed as a tobacco product to be used by smokers in situations where they cannot, or do not want to, smoke. The Ariva package states that it contains "20 Cigalett™ pieces (Compressed Powdered

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[27] QUESTIONS AND ANSWERS, *supra* note 4, at 3.

Tobacco"), and that Ariva is "A Smokeless Tobacco Product" for use "when you might otherwise have a cigarette but can't."[28] And because Ariva is a tobacco product, it is sold not in the candy aisle of stores, but with other tobacco products pursuant to the rules, regulations and taxes that are applicable to the sale of tobacco products. See *supra* at 5.

These facts distinguish Ariva from the "Masterpiece Tobacs" and GumSmoke products cited in the Petition (at 12-16). FDA rejected the manufacturer's claim that "Masterpiece Tobacs" was a smokeless tobacco product, and instead determined that "Masterpiece Tobacs" was a "food" because it looked, tasted, and chewed like a chewing gum, and it contained a chewing gum base as well as tobacco.[29] In making this determination, FDA relied on *United States* v. *Technical Egg Products, Inc.*, 171 F. Supp. 326, 328 (N.D. Ga. 1959), which held that items that are generally regarded as foods are "foods" within the meaning of the FDCA, even if the seller claims that he does not intend to sell the items for human consumption. Thus, the court held that rotten eggs, which the distributor claimed would not be sold

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[28] Ariva Label, *supra* note 9.

[29] Letter from John M. Taylor, Associate Commissioner for Regulatory Affairs, FDA, to Stuart Pape, April 12, 1988, at 1, 3 (Attachment G to the Petition).

for human consumption, were nonetheless "food" within the meaning of the FDCA because eggs are generally regarded as foods and "a rotten egg is one differing only in degree rather than in kind from a sound egg." *Id*; see also *United States* v. *52 Drums Maple Syrup*, 110 F.2d 914, 915 (2d Cir. 1940) (maple syrup containing unduly high concentrations of lead is a "food" even though the distributor claimed that he would remove the lead before selling it to consumers because maple syrup is generally regarded as a food).

Similarly, GumSmoke was "a tobacco-flavored chewing gum" that was intended to be marketed as a food.[30] As noted above, "chewing gum" is specifically classified as a "food" under the FDCA, 21 U.S.C. § 321(f)(2). But Ariva is not a chewing gum. Moreover, Ariva is not marketed as a food, and it is not the kind of product that is generally regarded as a food. Instead, it is a smokeless tobacco product that contains the same ingredients found in other smokeless tobacco products, is used primarily for tobacco satisfaction, as are other smokeless tobacco products, and is marketed and regulated as a tobacco product. There is, therefore, no basis for concluding that Ariva is a "food" under the FDCA.

b. Although *Brown & Williamson* did not specifically address the question whether FDA has authority to regulate tobacco products as "foods"

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[30] Budich Letter, *supra* note 24, at 1.

under the FDCA, the analysis the Court used in holding that tobacco products are not "drugs" compels the conclusion that they are not "foods" either. If the Petition were granted, Star Scientific could not sell Ariva unless it obtains FDA's permission to use tobacco in Ariva. To obtain such permission, Star Scientific would have to file a lengthy food additive petition for tobacco, containing, among other things:

> (B) a statement of the conditions of the proposed use of [tobacco], including all directions, recommendations, and suggestions proposed for the use of [tobacco], and including specimens of its proposed labeling;
>
> (C) all relevant data bearing on the physical or other technical effect [tobacco] is intended to produce, and the quantity of [tobacco] required to produce such effect;
>
> * * *
>
> (E) full reports of investigations made with respect to the safety for use of [tobacco], including full information as to the methods and controls used in conducting such investigations.

21 U.S.C. § 348(b)(2). And even after such a petition were filed, Star Scientific still could not sell Ariva unless FDA determines that tobacco can be safely used as a food additive in Ariva. 21 U.S.C. § 348 (c). This result would be inconsistent with laws that "foreclose[] the removal of tobacco products from the market." *Brown & Williamson*, 529 U.S. at 137.

Moreover, after extensively reviewing the history of the nation's tobacco laws, the Court in *Brown & Williamson* concluded:

> Owing to its unique place in American history and society, tobacco has its own unique political history. Congress, for better or for worse, has created a distinct regulatory scheme for tobacco products, squarely rejected proposals to give the FDA jurisdiction over tobacco, and repeatedly acted to preclude any agency from exercising significant policymaking authority in this area. Given this history and the breadth of the authority that the FDA has asserted, we are obliged to defer not to the agency's expansive construction of the statute, but to Congress' consistent judgment to deny the FDA this power.

529 U.S. at 159-160. That reasoning is equally applicable to the "food" provisions of the FDCA. Tobacco products are simply not covered by that statute.

* * * * *

As we have already explained, Star Scientific acknowledges that all tobacco products -- including Ariva -- pose risks to human health. For this reason, Star Scientific supports efforts to give FDA jurisdiction to implement fair and meaningful regulations over the manufacture, sale, distribution, labeling and marketing of *all* tobacco products. But as the Supreme Court explained in *Bown & Williamson*, Congress has made a different choice. Instead of subjecting smokeless tobacco products to FDA regulation under the FDCA, Congress enacted the CSTHEA, which requires, among other things, that smokeless tobacco products contain specified

health warnings (15 U.S.C. § 4402(a)(1)), and that manufacturers provide the Secretary of Health and Human Services with a list of the ingredients and the amount of nicotine contained in their smokeless tobacco products (*id.* § 4403(a)). The Secretary may then conduct research and report to Congress information about any ingredient he believes to pose "a health risk to users of smokeless tobacco", or any other information he "determines to be in the public interest." *Id.* § 4403(b)(1).

Although the CSTHEA is not Petitioners' preferred way to protect the public from the dangers of smokeless tobacco products, that is the system chosen by Congress, and it must be applied equally to Ariva and all other smokeless tobacco products. As explained above, Petitioners' attempt to limit the CSTHEA to what they believe to be "traditional" tobacco products, while extending the FDCA to tobacco products like Ariva finds no support in the text of the CSTHEA or the *Brown & Williamson* decision. What the Supreme Court said in *Brown & Williamson* is equally true in this case: "in our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop. Reading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain that Congress has not given the FDA the authority" to

regulate tobacco products absent claims of therapeutic benefit by the manufacturer. 529 U.S. at 161 (internal quotations and citations omitted).

CONCLUSION

For these reasons, the Petition for Regulation of Ariva should be denied.

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